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14 CEO's Message

CEO's Message

On September 12, 2022, I was appointed representative director, president and CEO of Santen Pharmaceutical. I am keenly aware of the magnitude of the responsibility this new role entails, and I intend to dedicate all my time and efforts to the further growth of the Company.

Our CORE PRINCIPLE is *Tenki ni Sanyo Suru* (Exploring the secrets and mechanisms of nature in order to contribute to people's health). Under this principle, we have endeavored to be of service to our patients and their loved ones. And as a specialty company focusing on ophthalmology, we contribute to *Happiness with Vision* by providing valuable products and services to patients and medical professionals around the world.



Takeshi Ito
President & CEO



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My Approach as President and CEO

I have a deep conviction of the large potential of this company, our capabilities, and the talent that will take Santen to renewed and sustainable growth.

I feel both responsible and capable for putting the company back on a growth trajectory for our investors, for our duty to the long history of Santen, and for the employees who support our company. This is why I accepted this new role, and I believe we can achieve these goals.

I have always considered it my mission to provide ever-higher levels of essential value through our products and services. My belief in this mission is what motivates me and also what has driven my work at Santen.

In 2012, I was appointed as Head of Prescription Pharmaceuticals Sales Department, Sales and Marketing Division, Prescription Pharmaceuticals, in what

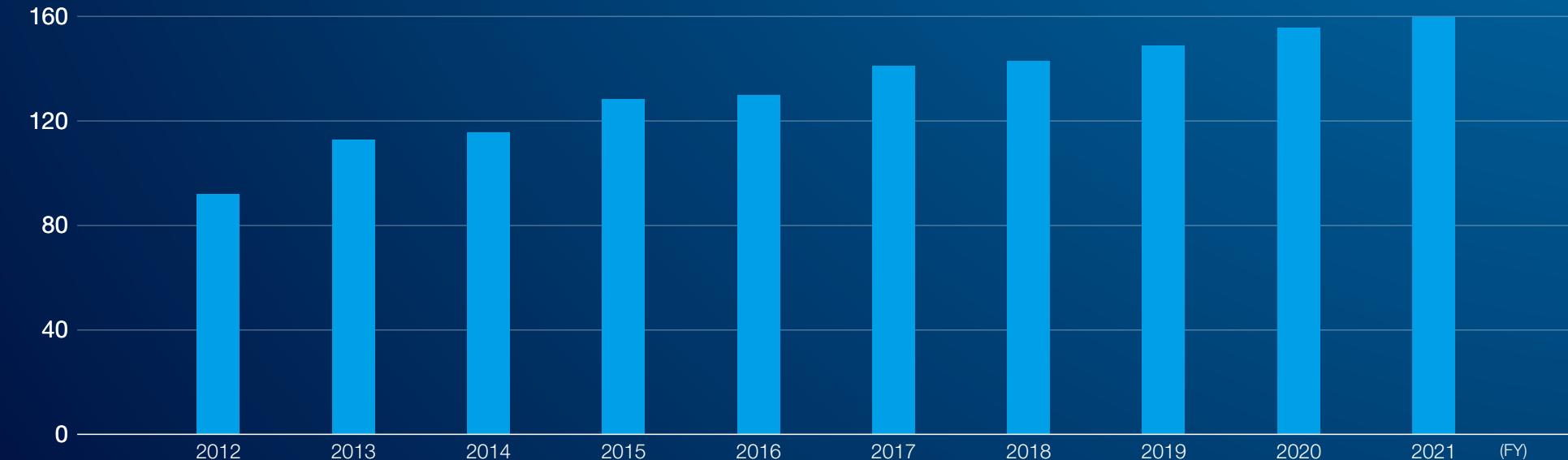
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I feel both responsible and capable for putting Santen back on a growth trajectory.

was deemed to be a difficult business environment in Japan. The number of our domestic medical representatives remained at around 400, never varying significantly over time, but I increased Japan ophthalmology business sales from JPY 90 billion to JPY 160 billion by filling our development pipeline, building an efficient and effective sales network, and managing via KPIs and the PDCA (Plan-Do-Check-Action) cycle. And while the global environment of today is challenging, it seems similar to what we experienced in Japan, and we look forward to the many growth opportunities waiting to be exploited.

Japan Ophthalmology Business Sales

(JPY billions)



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Fiscal 2021 Review and of Current Issues

Santen recorded a year-on-year increase in revenue and a decrease in profit for fiscal 2021, the first year of our MTP2025 medium-term management plan. While revenue grew 7% to JPY 266.3 billion, core operating income decreased 7% to JPY 46.3 billion. Rest assured that our management team takes this decrease in profit as a very serious matter.

Sales and profitability in our core overseas businesses are improving. But we still face challenges in productivity and profitability Company-wide. Our business in China (►Page 27) experienced a negative impact due to volume-based purchasing mainly with respect to Cravit. However, the steady shift to multi-channel sales allowed the business to recover. At the same time, the launch of our business in the U.S. (►Page 30) has not progressed as planned due to delays in the development and release of new products. This delay has slowed

our growth momentum temporarily. Therefore, we will place the highest priority on rebuilding profitability. In May, we began selling Verkazia, a treatment for vernal keratoconjunctivitis. We also re-submitted an application to the FDA for our glaucoma treatment, STN1011700, which received approval on September 22.

From the viewpoint of sustainability, we added an ESG indicator as a component of executive compensation (►Page 64). We believe this new component will strengthen our framework for pursuing ESG management as a united company. On the environmental front, we formulated the Santen Vision for the Earth 2050, coinciding with the announcement of MTP2025. And the Company is already engaged in activities to achieve targets related to climate change and reducing our environmental footprint. Santen also began using biomass plastic for eye drop bottles. As of today, we use biomass plastic for seven products.

	FY2020		vs. Revenue		FY2021		vs. Revenue		(JPY billions)	
	Revenue	Core operating profit	Operating profit	Net profit	Revenue	Core operating profit	Operating profit	Net profit	Revenue	Core operating profit
Revenue	249.6				266.3				264.0	
Core operating profit	50.1	20%	12.2	4%	46.3	17%	35.9	13%	45.5	17%
Operating profit										
Net profit	9.1	4%	3.2	1%	27.2	10%	24.4	9%		

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Challenges and Risks

We have taken on a variety of challenges over the past several years. At the same time, we have not considered and evaluated opportunities sufficiently from the perspective of consumers and patients, and we have not prioritized projects sufficiently, either. As a result, our resources have been dispersed, and we have not built a system to properly manage and monitor KPIs, etc., which has kept us from implementing new initiatives consistently.

Given an awareness of these issues, I intend to organize our policies and reiterate our growth plan under my leadership. We will be more consistent in our study and evaluation of the opportunities we face and strengthen prioritization of projects. We must also refine our execution capabilities, mobilizing limited resources and establishing systems to manage and regularly monitor KPIs appropriately.

In terms of risk assumptions, we face the same risks common to the pharmaceutical industry, namely pipeline and geopolitical risks. We intend to build a risk-based portfolio for pipelines, including potential future changes. With regard to geopolitical risk, we plan to study the formation of supply chains tailored to each region as necessary.

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We will be more consistent in our study and evaluation of the opportunities we face and strengthen prioritization of projects.



We accept that we have not met your expectations in terms of earnings. I have my own understanding of the challenges Santen faces and I intend to do everything in my power to meet your expectations.

As a first step, we will map out a detailed action plan, evaluate the challenges we faced looking back over the past three years, and assess what we have done well and what we have done poorly. In this way, we will make a course correction to return to a growth trajectory.

The Santen Approach to Raising Corporate Value Over the Long Term

Santen also pursues initiatives related to sustainability. On the environmental side, in June this year, we endorsed the Task Force on Climate-related Financial Disclosures (►Page 49) and began disclosing risk scenarios along with other information. To reduce the environmental impact of our business operations, we use biomass plastic for eye drop bottles. At the same time, we are working toward a 15% reduction in plastic for packaging and packing materials by 2030, compared with 2019 levels. In February 2022, we completed a switchover to renewable energy for electricity used at our plants in Japan. You might not know that steam is essential for the production of eye drops and other products. As the transition to low-carbon energy accelerates, we envision the use of hydrogen boilers and hydrogen fuel storage facilities to transition from fossil-fuel boiler-driven energy to low-carbon energy. Santen is a member of the global community, and we will continue to fulfill our environmental responsibilities to the best of our ability.

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With employees of the Japan Business at the business division awards

Looking at human resources, I intend to emphasize relationships with our people above all else. I want to share the joy of providing consumers and patients with essential value at a level never-before provided through our products and services, which I view as a personal mission. And together with our people, we will deliver success under our new plan, tying the efforts of all to business results.

At the same time, we continue initiatives to strengthen corporate governance further. In June this fiscal year, we added two Outside Directors. Our Outside Directors now represent over 70%¹ of the Board, and the addition of a woman non-Japanese Director has increased **Board diversity** (►Page 59). The business environment will be challenging this fiscal year, and our Board of Directors is engaged in active and in-depth discussions to ensure we steer company management in the right direction.

¹ As of September 30, 2022

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We have started purchasing shares up to a total payout ratio of 150% this fiscal year.

To Our Shareholders

As announced in May this year, we have started to buy back shares as a means of capital allocation, purchasing shares up to a total payout ratio of 150% this fiscal year. Santen will act in a flexible manner, taking into account the stock price, market conditions, and other factors. While our basic policy is to make strategic investments in carefully selected projects based on our medium-term management plan, I will also focus on shareholder returns.

Last, I will say that in this rapidly changing world, it is essential that Santen engages with speed and consistent execution if we are to continue contributing to society as the leader in ophthalmology. Having been a member of the Santen management team for many years, I am convinced we have the talent and skills to accomplish our goals.

We will continue to do our utmost to meet the expectations of our shareholders, investors, and other stakeholders, and we look forward to your continued support.

Takeshi Ito
President & CEO

CFO's Message (Financial Strategy for Medium-to-Long-Term Growth)

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FY2021 Results and FY2022 Outlook

FY2021 marked the start of our medium-term plan MTP2025 with our share price underperforming the market and industry averages. Revenue was JPY 266.3 billion and grew 7% over the previous year, led by overseas sales, with core operating profit falling 7% to JPY 46.3 billion. The decrease in profit was mainly due to reduced pollen levels in Japan impacting core product line *Alesion* sales in contrast to the previous

year, COVID-19-related impact on certain regions' sales, and a delay in the earnings contribution of U.S.-based Eyevance acquired in FY2020.

For FY2022, the second year of MTP2025, we expect revenue to remain flat at JPY 264.0 billion, and core operating profit to decline 2% to JPY 45.5 billion. While we expect continued growth centered on Asia and EMEA for our overseas business, we project a decline in profit due to substantial impact from NHI drug price revisions in the Japanese market and an increase in upfront investments, including research and development expenses as new drugs in our pipeline advance to the next phase.

Meanwhile, we are making steady progress in the construction of new plants in Japan and China, our first major capital investments in 20 years, funded by a stable FY2021 and FY2022 operating cash flow. In addition, we have strengthened our new products pipeline for future growth through in-house development and in-licensing.

We also acknowledge the capital markets evaluation: we have not delivered one of our most important priorities which is shareholder value maximization.



Kazuo Koshiji

Chief Financial Officer (CFO)
& Chief Risk Officer

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CFO's Message

FY2022 Financial Approach

Improving our share price in light of its last 12-month trend remains our priority. While we recognize share price is determined by multiple factors, we intend to take the necessary actions towards (1) Earnings per share (EPS) and return on invested capital (ROIC) improvements and (2) Capital allocation with a greater focus on our shareholders.

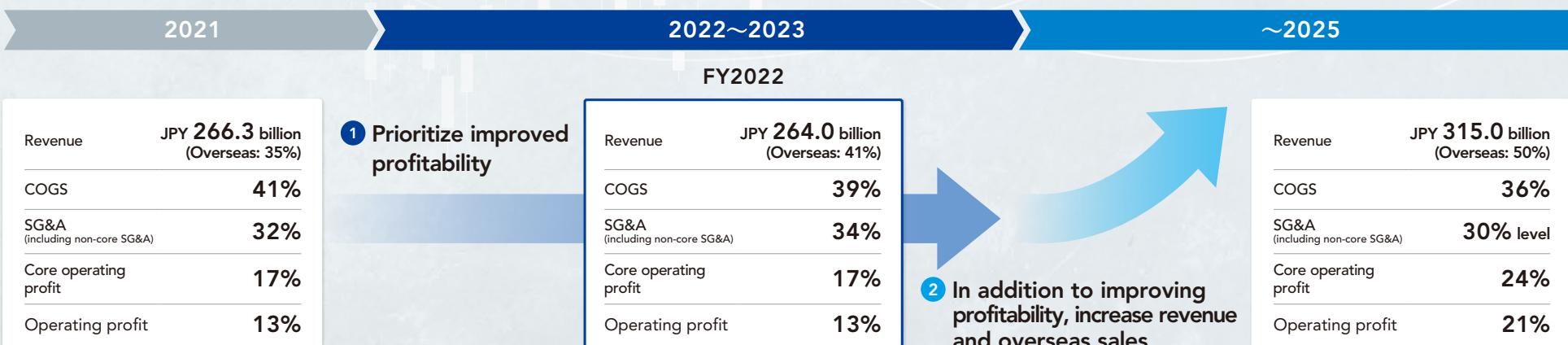
Pertaining to our businesses, the previously stated projections are minimum targets. We aim to bring core operating profit to JPY 50 billion levels as early as FY2023. We will focus on improving profit margins across all income streams and taking necessary measures to manage the appropriate size of our balance sheet in a disciplined manner. Consequently, we will conduct a zero-based review of expenses including structural reforms, screen investments based on economic rationale, and improve existing asset turnover. We will also continue to take the necessary measures with a stronger commitment to capital efficiency. For investment in business development, in addition to verifying ROIC, we will control the consolidated intangible assets ratio on our balance sheet, and implement financial discipline to eliminate inefficiencies. We will also continue to optimize working capital.

Our capital policy will support improvements in EPS, ROIC, and consequently ROE by adjusting our outstanding number of shares and total capital through share buybacks. Although the quantitative impact would be limited, we will also promote divestments of cross-shareholdings from the standpoint of balance sheet discipline.

We will continue to prioritize investment for future growth in our cash flow allocation. However, since large-scale investments in business development are contingent on available opportunities, economic conditions and other factors, any resulting surplus funds generated from unrealized investments will be returned to shareholders. For FY2022, we project a cash allocation that would allow a minimum total payout ratio of approximately 150%, factoring in a dividend payout ratio of 40% and share buybacks. This reflects our recognition that the speed with which we have realized returns on upfront investments in recent years has fallen short of capital markets' expectations, whilst also taking into account Santen's minimum required level of working capital.

We will allocate capital in a way that contributes to improved capital efficiency. We will evidently optimize growth investments and shareholder returns while monitoring investment opportunities and profitability.

Positioning of Fiscal 2022 in MTP2025: FY2022–2023, Transitioning to a Resilient Financial Structure



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CFO's Message

Medium-Term Financial Strategy

1 Capital Efficiency

Santen seeks to maximize shareholder value by maximizing cash flow and reducing the cost of capital, using return on equity (ROE) as its most important indicator.

Our fundamental approach remains unchanged. We will continue to focus on ophthalmology as we work to increase profitability, maximize cash generation capabilities and improve capital efficiency (ROE) to maximize shareholder value. I will work to optimize Santen's capital structure for financial soundness, while seeking the appropriate balance between upfront investments/retained earnings for future growth, and shareholder returns.

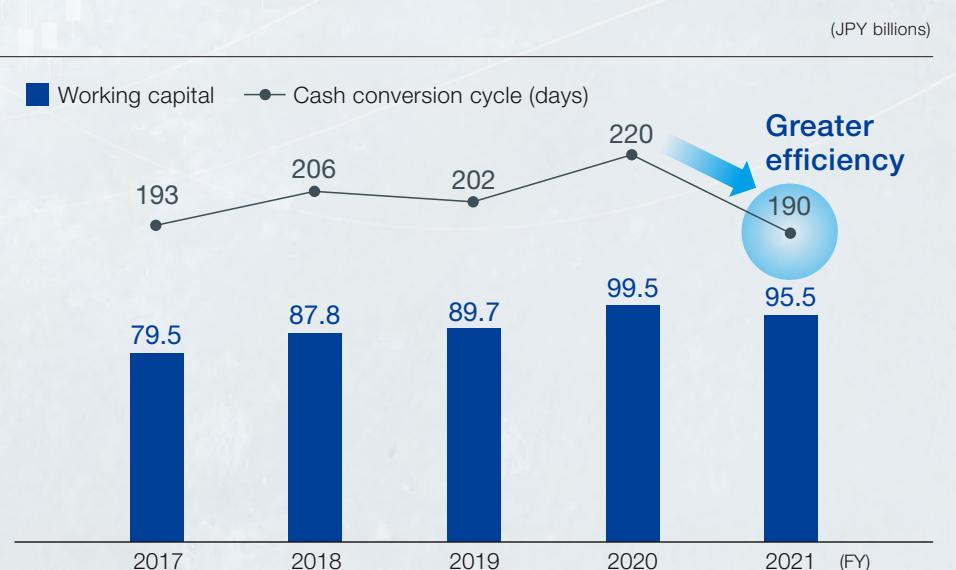
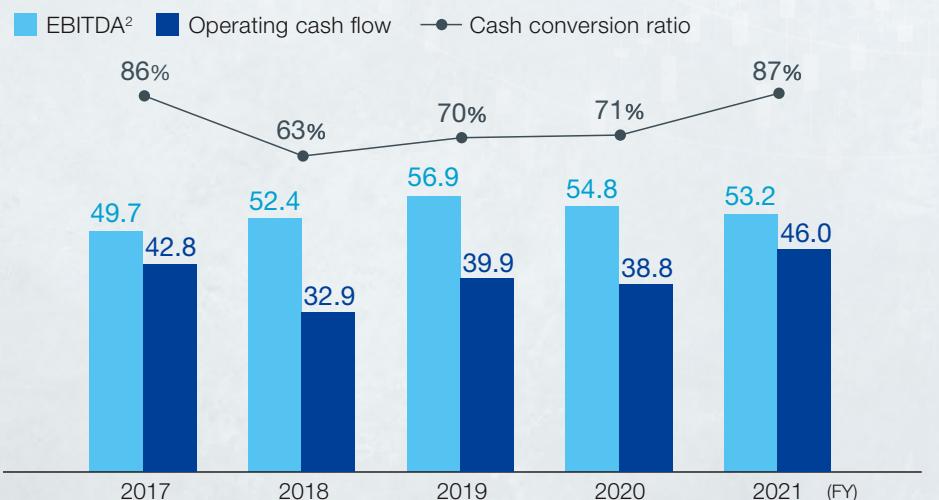
Santen aims to achieve an ROE target of 13% by the end of MTP2025 and 20% in FY2030. As precedently mentioned, although the earnings contribution of our U.S. business was delayed and the impact of drug price revisions in Japan was larger than anticipated, we will transform our earnings structure to be more

resilient and capable of generating profits irrespective of the business environment. On the basis that there is still ample room to increase profitability by reducing SG&A expenses, we aim to reduce the ratio of SG&A to revenue to a 30% level. We will also reduce the cost of goods sold (COGS) ratio to a 36% level by reducing manufacturing costs as well as changing the product mix. This should improve our core operating profit ratio by about 4 percentage points. We also expect to raise the net profit ratio by 5 percentage points or more by reducing the effective tax rate to the low 20% range by fiscal 2025, and target a compound annual growth rate (CAGR) for revenue of about 5% with an operating profit growth rate of approximately 10%.¹

We intend also to reduce the cost of capital through financial leverage in conjunction with aiming to maintain an A+ credit rating from R&I as an indication of our financial health and relevant low funding costs, thereby maximizing our ability to make investments.

¹ Core basis: Non-recurring charges significantly reduced profit in FY2020.

Cash Flow: Stable Cash Generation Ability



²EBITDA = (Operating profit) - (Other income) + (Other expenses) + (Depreciation and amortization)

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CFO's Message

2 Cash Maximization & Capital Cost Reduction

Our sources of cash will principally consist of net operating cash inflows, to be supplemented by external funding whilst maintaining financial health and stability. We will also mitigate long-term funding risk through staggered redemptions and repayments. In addition, we are centralizing financing at our International Financial Head Quarter (IFHQ) in Switzerland, thereby improving capital efficiency by funding respective regional capital needs using a cash management system.

Shareholders and the market expect value creation from investments in business opportunities that only Santen can turn into successes. This is why investment is our top priority in capital allocation. We have entered our first large-scale capital investment cycle in 20 years, which includes expanding production capacity in Japan and China and upgrading to a next-generation ERP system. We will also continue to invest strategically to acquire external resources that contribute to growth in our businesses, taking into account our balance sheet capacity, including intangible assets. We will evaluate investments to ensure that they are accretive in the near term, and enhance

asset turnover in existing businesses, which should mitigate the negative impact on capital efficiency from asset growth.

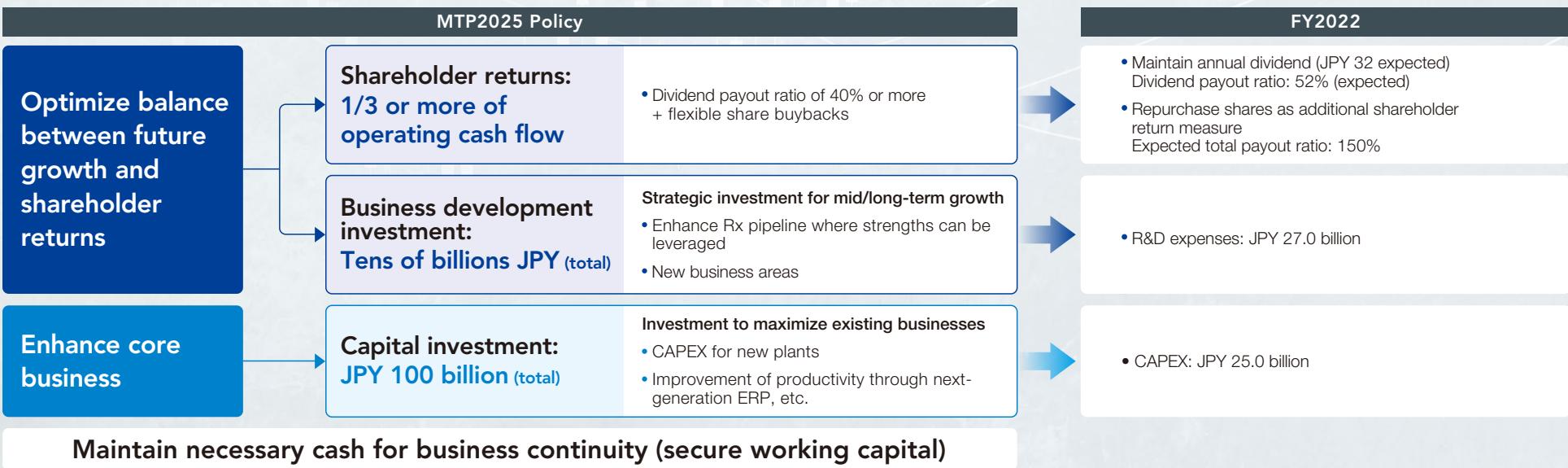
3 Shareholder Returns

Delivering shareholder returns is a priority for Santen's management.

In MTP2025, we are focusing on improving total shareholder return (TSR) through direct distribution of profits and medium-to-long-term share price appreciation.

First, we will maximize profits by enhancing the profitability of the investments previously mentioned. We expect this will contribute to medium-term share price gains. Dividends are the primary form of shareholder returns, but we also intend to deploy our internal capital reserves to further enhance returns through share repurchases, subject to market conditions, in order to reward medium- and long-term shareholders. For FY2022, we are targeting a total payout ratio of approximately 150%, but in the medium term, we plan to return approximately one-third of operating cash flow to shareholders with a dividend payout ratio of 40% as a base.

Cash Allocation: Proactive Allocation to Strategic Investments and Shareholder Returns



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23 Feature 1: Strengths in Japan

Feature 1

Strengths in Japan



■ Shinichi Teramachi

Head of Sales Department,
Japan Sales and Marketing Division

■ Takeshi Ito

President & CEO

■ Ippei Kurihara

Head of Japan Business,
Head of Japan Sales and Marketing Division,
Head of Marketing Department

We will effectively leverage our knowledge and experience in the Japan business, that has driven Santen's growth, to deploy our firmwide business strategies and bolster our competitiveness as a global ophthalmology company.

Strategy

Ito: Japan has been the cornerstone of Santen's business and growth. Its greatest strength consists of its high quality and sophistication in product and marketing strategy followed by a thorough execution yielding results. This is largely the result of many years of changes we have undergone, regardless of the environment.

Kurihara: Fundamentally, all products exist to resolve a particular issue in eye care, and our evident objective should be to deliver what allows for a better treatment. Nevertheless, in terms of outcomes, there is a vast difference between product-centric sales promotion, and a set of actions and behavior resulting from a treatment vision-centric strategy. The strength of our Japan business is that we all

* This discussion was held in June 2022.

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23 Feature 1: Strengths in Japan

Strategy

Feature 1

Strengths in Japan



seek to propose better treatments from the patients' standpoint.

Ito: Our first consideration is the type of therapeutic value and satisfaction this product can bring to the patient. In order to meet this, we need to share the same understanding with doctors on the product's implication for the status quo, and its usage for actual treatment. Naturally, we also place importance on formulating concrete plans to realize our vision.

Kurihara: The considerations pertaining to a product launch including its preparations, consist of identifying the effective treatment and laying out the respective scenarios, and set of action plan. As a result of this approach, we have

a number of products that have achieved sales beyond our initial expectations.

Ito: Creating a vision for better treatment from the patient's standpoint, mapping out a clear process to reach the objective, and our capabilities for a thorough process implementation is something that is firmly rooted in a variety of our business activities. *Alesion* is a good example.

Kurihara: Conventionally, anti-allergy eye drops were applied once itching is felt, but from the patient's perspective, we thought it would be preferable to avoid any feelings of itchiness during the onset period. We thought on how this itchiness felt by a patient could be reduced which led us to promote proactive application as part of an appropriate eye drop usage. *Alesion* yielded results that greatly surpassed our original expectations. This outcome can be accredited not only to our Marketing Department but also to our medical representatives (MRs) and their entire division's ability to share and work toward the goal of better treatment from the patient's standpoint.

Ito: Sharing a picture of better treatment from that standpoint is also starting to make a difference in the activities and mindset of our MRs.

Teramachi: Our MRs in Japan share a common mission: To correctly understand and convey the value and potential of products, and to resolve challenges facing both patients and medical professionals. MRs share the same desire to alleviate the symptoms and burden concerning eye-related problems as the medical professionals who engage with patients every day. I believe that thinking from the perspective of patients will make it easier for them to understand the issues patients face. MRs place importance on collecting and providing information based

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23 Feature 1: Strengths in Japan

Feature 1

Strengths in Japan

on dialogues with medical professionals on how to realize better treatment, and that leads to proposals for solutions from the patients' perspective.

Ito: Other strengths of our MRs in Japan include their attention to detail in executing strategies and their thorough implementation of the Plan-Do-Check-Action (PDCA) cycle. We have taken a number of measures to ensure that each MR understands our strategies and incorporates them in their daily activities.

Teramachi: A PDCA process has been meticulously designed to maximize the outcomes of strategies. A management plan is established for each product. First, it is important that MRs understand the strategy. We take great care to make sure that they fully understand the significance of what they do. Strategies must be converted into action by MRs. Therefore, in pharmaceutical detailing,¹ for example, we have defined and are sharing the "model" that took shape after examining various ideas for the behavior MRs should adhere to according to our strategies.

¹ Provision of pharmaceutical information to medical professionals and pharmacists by MRs of pharmaceutical companies

Strategy



A systematic structure that includes **training through cooperation between the head office and frontline operations** (►Page 47), support, and follow-up has been established to empower all MRs to take action based on this model. MRs prepare extensively before meetings and engage with medical professionals. In addition, the aspects of their activities that have been positively evaluated by patients and medical professionals, as well as issues that should be addressed, are quickly shared with the sales organization as well as strategic planning and support departments to be used for further improvements. These are just examples, but the PDCA management of our overall sales organization is full of innovation that we put into practice while making necessary improvements.

Ito: To achieve further global growth, it will be important for Santen to use its creativity to paint a picture for better treatment that fits the specific needs of patients and stakeholders in each region. In pursuing that objective, I think the comprehensive PDCA cycle that we are implementing in Japan can also be applied in other regions to bolster our firmwide results.

Strategy

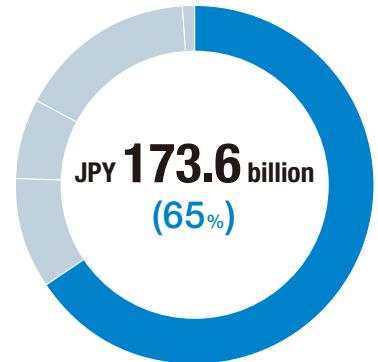
26 Strategies by Region

Strategy

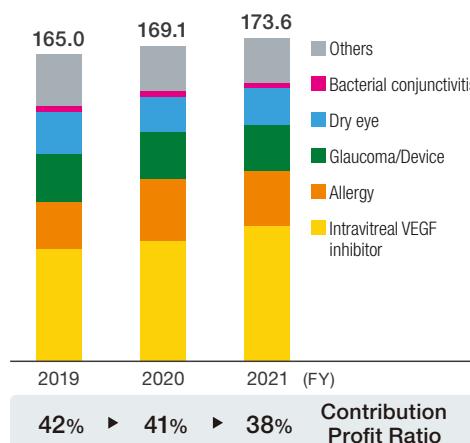
Strategies by Region Japan



FY2021 Revenue (Share of Total)



Revenue (JPY billions)



Opportunities

- Increase in people with eye problems due to increased use of digital technology and visual display terminals
- Recovery in demand from overseas visitors as Japan relaxes entrance restrictions (OTC pharmaceuticals)
- Discovery of potential patients and improvement in adherence rates as a result of greater disease awareness and understanding
- Expansion of consultations as a result of the availability of online consultations and other services that offer improved convenience of medical care
- Increase in eye exams in new patient segments and discovery of potential patients, following the development of drugs in areas that lack widely available treatments, such as myopia, presbyopia and ptosis

Risks

- Patent expiration of core products and launch of generics
- Reform of National Health Insurance system and drug pricing system (e.g., possible extension of reimbursement pricing revisions to all drugs)
- Replacement with generics to the same degree as in other therapeutic areas (80% or more) due to government policies to promote the use of generics

Business Strategy and Overview

The Japan business, which is mainly centered on the prescription pharmaceuticals, over-the-counter (OTC) pharmaceuticals, and surgical domains, accounts for approximately 65% of consolidated revenue. In prescription pharmaceuticals, which accounts for the bulk of sales, we maintain the top market share¹ and high customer satisfaction. In that regard, our 400 medical representatives nationwide deliver services as an “Ophthalmic Solutions Provider,” while focusing on the needs of patients and medical professionals. Sales and marketing, medical affairs, development and other functions cooperate to gain a firm understanding of medical challenges, which they apply in developing high-value-added products and providing information. This has led to business growth and increased productivity. For example, STN1008903, a dry eye treatment approved in June 2022, is an improved formulation of *Diquas*. It reduces the frequency of application from six times a day to three. One of the challenges in treating dry eye syndrome is poor adherence to the dosing regimen and consequently, the desired therapeutic effect is not obtained.² In response, Santen developed a formulation that is expected to improve therapeutic

outcomes by reducing the burden on patients and promoting adherence to the dosing regimen.

In fiscal 2021, although revenue from *Alesion* decreased sharply due to lower-than-average pollen counts, revenue for the Japan business as a whole increased 2.7% over the previous year due to the contribution of other major products. Over the next few years, we expect to face National Health Insurance (NHI) drug price revisions, including a significant reduction in the reimbursement price of *Alesion*, and patent expirations of core products such as *Diquas*, *Tapros* and *Tapcom*. This will make for a difficult operating environment, with sales in fiscal 2022 projected to decline 10% year on year. However, by launching new products and providing tools that support treatment and care for glaucoma and dry eye, we will continue to resolve the challenges faced by patients and eye care professionals, and thereby maintain and improve profitability. We will also put the knowledge we have cultivated in Japan to use in other regions to enhance Group-wide profitability and contribute to better ophthalmic care globally.

Value Creation Highlights

Using Digital Technology to Provide Information to Patients and Consumers

Santen develops various smartphone apps aimed at improving quality of life for patients and everyday users. Two examples are *Kayumidas* and *Hitomi Ururu Scan* (see images on right). *Kayumidas* targets pollinosis patients. Based on the daily weather forecast, the app provides users with alerts for eye conditions such as itchiness, as well as precautionary measures they can take. It also comes with a reminder for eye drop application and other functions that support “preemptive instillation” during the onset period. *Hitomi Ururu Scan* promotes care by using image recognition technology to check for low eye moisture, which is closely associated with eye dryness and eye strain, and suggests ways to maintain and improve eye moisture.



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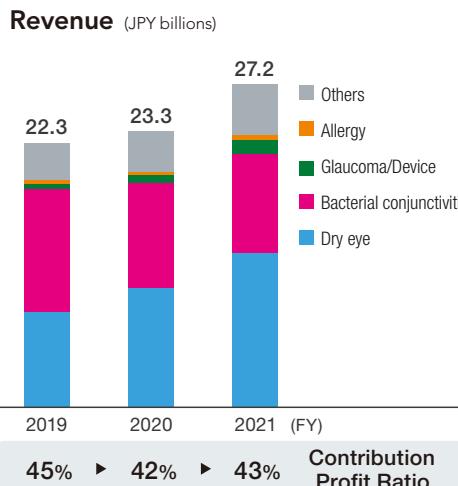
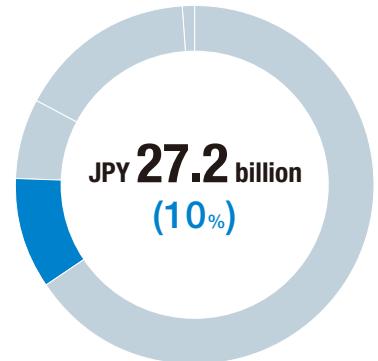
26 Strategies by Region

Strategy

Strategies by Region

China

FY2021 Revenue (Share of Total)



Opportunities

- Market growth driven by increasing number of patients due to aging population and development of ophthalmic ecosystem
- National-level initiatives targeting myopia and other eye conditions
- Rising demand for high-value-added pharmaceuticals and shift of patients to high-end private hospitals, reflecting rapid economic growth
- Insurance reimbursement for innovative products and acceleration of new product launches due to evolution of the drug approval system

Risks

- Drug reimbursement price reductions among existing products and impact on sales due to changes in healthcare policy and the insurance system
- COVID-19-related restrictions in major cities due to renewed outbreak and impacts on business
- Delay in construction of new plant in Suzhou due to the global semiconductor shortage and COVID-19-related restrictions
- Soaring labor costs amid economic growth and intensifying competition to acquire highly skilled personnel

Business Strategy and Overview

The China business began scientific and marketing activities following the establishment of the Beijing Representative Office (no longer in operation) in 1996. Following the establishment of Santen Pharmaceutical (China) Co., Ltd. in 2005, completion of the Suzhou Plant and the start of integrated production, as well as sales and marketing activities, enabled Santen to further grasp customer needs in China and offer greater value. As a result, we maintain a large market share¹ and high customer satisfaction. In anticipation of continuing reforms to China's healthcare system, we will shift from concentration on large national public hospitals to a multichannel customer strategy. In addition, we will pursue differentiation by strengthening development of the ophthalmic ecosystem (such as through support for the training of eye care professionals and initiatives to identify potential patients), by enhancing research and development functions, and by using digital technology and scientific evidence to expand sales of new products. With this approach, we aim to achieve sustainable growth while unlocking high growth potential.

We expect long-term expansion of product demand in the China market with the emergence of potential patients and new markets in areas such as myopia, reflecting the large population, rapid aging of the population, and the development of the ophthalmic ecosystem. In the context of our operations in

China as a pharmaceutical company specialized in ophthalmology, our Suzhou Plant is unparalleled in its technological capabilities, quality and production capacity for ready-to-sell products. Additionally, our new plant in Suzhou, currently under construction and scheduled to start operations in 2025, will reduce costs through increased automation and labor saving, and incorporate environmental considerations such as CO₂ emission reductions. With a production capacity of up to 840 million units (5mL unit equivalent) per year, it will further solidify our competitive advantage in China.

In fiscal 2021, the China business recovered rapidly from the impact of volume-based purchasing that began in the second half of fiscal 2020, achieving growth of 16.5% year on year driven by expanded sales of new products such as *Diquas* and *Tapros* and the steady implementation of the multichannel approach and other strategies. We have also been taking steps to boost productivity, including efforts to improve sales and marketing efficiency, and ensuring expenditure allocations are fully deployed according to revenue performance. Through the steady implementation of our strategies in fiscal 2022, we aim to expand sales of existing products and advance R&D projects to the next stage. The launch of *Verkazia*, which obtained approval in China in April 2022, will contribute to the treatment of vernal keratoconjunctivitis (VKC) and help improve quality of life for patients and their families.

Value Creation Highlights

Building a Society Inclusive of Blind and Visually Impaired People: Establishment of Education Centers

In April 2021, the Suzhou Industrial Park Youth and Kid Extracurricular Education Center was established by Santen and the Suzhou Industrial Park Education Department. Its purpose is to promote knowledge and management of eye health among young people. On the same day, Santen and the Beijing Hongdandan Cultural Service Center for the Visually Impaired established an education center for visually impaired people with the objective of enhancing social understanding and support for the visually impaired.



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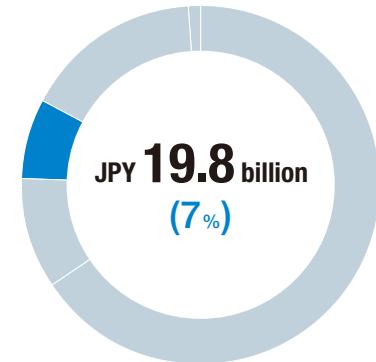
26 Strategies by Region

Strategy

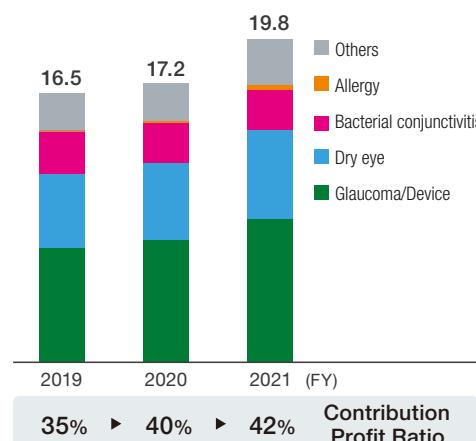
Strategies by Region

Asia

FY2021 Revenue (Share of Total)



Revenue (JPY billions)



Opportunities

- Improved diagnosis and treatment rates for eye conditions as the ophthalmic ecosystem develops
- Increasing interest in eye care in conjunction with economic development and rising household income, primarily in Southeast Asia
- Diversification of sales channels such as e-commerce and online pharmacies in tandem with advances in digital technologies

Risks

- Drug reimbursement price reductions and accelerated promotion of generics in government hospitals due to deteriorating national health insurance finances
- Improvement in quality of generics
- Stricter regulatory reviews that take cost-effectiveness into consideration in drug approval and insurance coverage

Business Strategy and Overview

In its Asia business, Santen operates in more than 15 countries and regions, including South Korea, Taiwan and Hong Kong in East Asia, and Vietnam, Thailand and other countries in Southeast Asia. We entered various markets starting in the 1990s, then began our own sales activities in South Korea in 2010 and in Thailand, the Philippines and elsewhere from the mid-2010s. We have steadily implemented strategies geared to needs specific to the Asia region, such as the launch of single-dose products for glaucoma and dry eye. As a result, we hold the top market share in South Korea and the Philippines, and have increased our market share¹ and gained a high level of customer satisfaction in many markets. We will continue to launch new products that accurately address the needs of patients and healthcare professionals, and support the development of the ophthalmic ecosystem to improve diagnosis and treatment rates. In Asia, there are not enough high-quality healthcare professionals to develop the ophthalmic ecosystem, and Santen is taking various measures to address that issue. In 2021, we began educational support for ophthalmic technicians in cooperation with the Singapore National Eye Centre. Such personnel play an important role in

ophthalmology; however, in many regions systematic training opportunities are inadequate in comparison to those for ophthalmologists. By supporting training of ophthalmic technicians, we will contribute to the expansion of eye care capacity in Southeast Asia.

In fiscal 2021, although some areas were significantly impacted by COVID-19, revenue increased 15.1% year on year as sales of core products for glaucoma and dry eye outpaced market growth¹ in major markets. The COVID-19 pandemic led us to digitalize and rethink sales activities, which improved the contribution profit ratio. Going forward, we will accelerate our shift in emphasis from expansion of sales volume to enhancement of quality. From the standpoint of providing new value that will support medium- and long-term growth, we will strengthen our business in glaucoma, an important therapeutic area, with the launch of *Eybelis* (in South Korea, Taiwan and Thailand), obtain approval of *PRESERFLO MicroShunt* in Singapore and other markets, and file for approval of ROCK inhibitor STN1013900. In addition, we are developing a treatment for ptosis, a new disease area for us, with the aim of filing an application in fiscal 2022.

Value Creation Highlights

An App That Provides Eye Care Information

In Asia, we are using digital technology to deepen communication with healthcare professionals. As part of those efforts, we are offering *Santen MD*, an app that provides the latest medical information to eye care professionals. The app features a wide range of content, including educational materials provided by Santen, webinars conducted jointly with academic societies, articles and videos about eye conditions, and columns by key opinion leaders. Approximately 6,800 healthcare professionals have registered for the app since its release in early 2020, representing more than half of the ophthalmologists in the supported area.²

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² Countries and regions where Santen conducts its own sales activities



Strategy

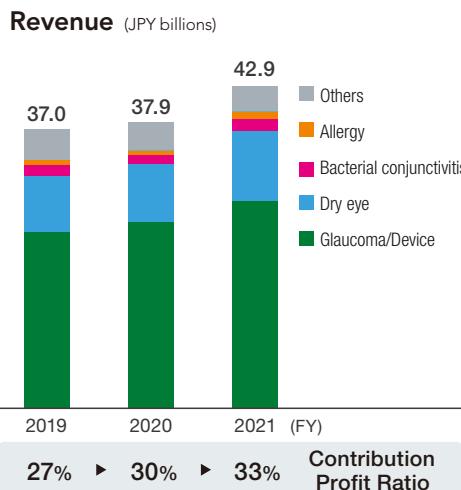
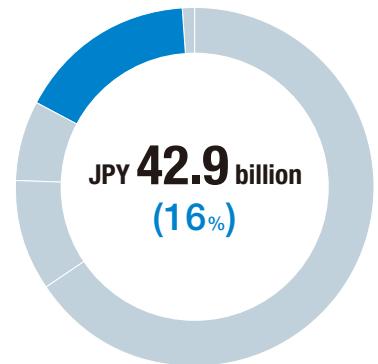
26 Strategies by Region

Strategy

Strategies by Region

EMEA

FY2021 Revenue (Share of Total)



Opportunities

- Opportunity for further penetration of the world's second-largest market¹
- Increase in glaucoma patient numbers due to aging population, and dry eye patients due to higher disease awareness
- Economic development and market growth in Middle Eastern and African countries

Risks

- Macroeconomic impact resulting from the situation in the Russia-Ukraine region that could affect countries' productivity, interest rates and cost of living
- Changes in insurance reimbursement coverage and reductions in reimbursement prices in response to deteriorating healthcare finances in various countries

Business Strategy and Overview

The scale of Santen's EMEA business is second only to that of Japan, with operations in about 50 countries and regions. The acquisition of Novagali Pharma S.A. (now Santen S.A.S.) and the ophthalmology assets of Merck & Co., Inc. of the U.S. in the 2010s expanded our product portfolio and geographic reach, and we have continued to strengthen our business foundation in this region. Currently, we are achieving growth in excess of market growth² rates with a product lineup that addresses regional needs, centered on single-dose products and preservative-free multi-dose (PFMD) products in the areas of glaucoma and dry eye. As a result, we achieved the top glaucoma market share in 13 countries.² For *PRESERFLO MicroShunt*, which was first launched in Europe, we have been providing product training to surgeons and expanding the number of facilities at which it is available since the controlled launch in 2018. We are aiming to grow sales to over JPY 5.0 billion in fiscal 2025.

The EMEA business encompasses many countries and regions, and while this enables us to diversify risk, each country has its own healthcare policies and insurance systems, so precise management is required across the

entire region. A market access strategy and marketing strategy for maintaining and improving product value over the medium and long term is especially important, and our diverse team of 26 leaders from 13 countries and regions works in close cooperation on a daily basis to grow and promote the business.

Fiscal 2021 revenue increased 13.2% year on year with growth centered on the core areas of glaucoma and dry eye. At this time, the impact of the situation in the Russia-Ukraine region on the Santen Group is not significant, but we are closely watching developments while ensuring our product supply capabilities, placing top priority on the safety of employees and their families. We are also actively entering new therapeutic areas. In addition to expanding sales of new products such as the antibiotic/steroid combination treatment *Ducressa*, we have in-licensed ROCK inhibitor products for glaucoma and an atropine myopia treatment. Going forward, we will leverage digital technology to increase productivity and share knowledge within the Group, focusing on functions for which we are particularly strong in Europe such as medical affairs and market access, as we continue our transformation into a truly global company.

Value Creation Highlights

Next-Generation Ophthalmology Education Platform

Since February 2022, we have been steadily rolling out the Santen Eyecare Education (SEE) portal for healthcare professionals in Europe. As digitalization progresses rapidly, there is a growing need for flexible online education programs. SEE enables European healthcare professionals to access best practices, as well as educational programs that incorporate gamified elements, thereby contributing to the development of ophthalmology healthcare education in the region.



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² Excluding S01P (retinal diseases)

Strategy

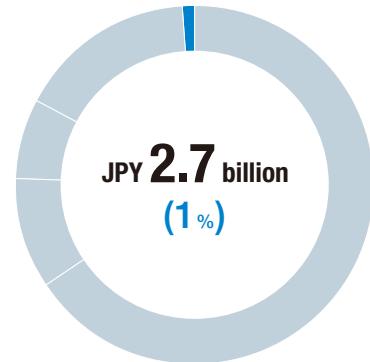
26 Strategies by Region

Strategy

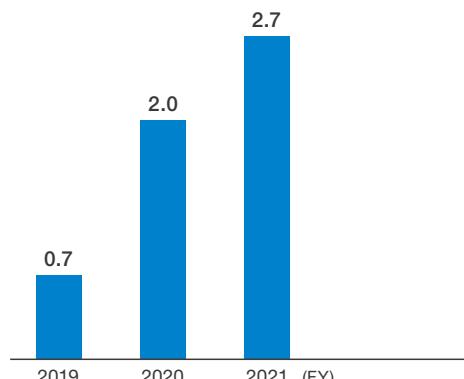
Strategies by Region

Americas

FY2021 Revenue (Share of Total)



Revenue (JPY billions)



* Mainly consists of revenue from products of the former Eyevance Pharmaceuticals and Cationorm.
The profit contribution is negative.



Opportunities

- Growth in the world's largest ophthalmic market¹
- Increase in volume of patients with eye conditions (e.g. glaucoma, etc.) due to an aging population

Risks

- Decrease in selling prices due to changes in insurance systems and tightening of criteria for formulary² listing
- Impacts of product distribution due to issues in the global supply chain
- Decline in competitiveness of existing products due to emergence of OTC products

Business Strategy and Overview

In the Americas business, 2019 marked the launch of Verkazia for the treatment of vernal keratoconjunctivitis (VKC) in Canada. In addition, we made a full-fledged re-entry into the U.S. market (following market withdrawal in the early 2000s) with the acquisition of Eyevance Pharmaceuticals Holdings Inc. in September 2020. The United States is a large market, accounting for nearly half of the global ophthalmic solutions market,¹ and is a critical market from the perspectives of building our global presence, exploring opportunities for future growth, and research and development. It is also a fiercely competitive market, so we decided on a strategy of pursuing differentiated products, building market understanding and cultivating a customer network. We acquired Eyevance as a base for developing our product pipeline and for sales and marketing infrastructure. Post-acquisition, integration was extremely challenging due to the COVID-19 pandemic, however, we successfully integrated Eyevance with the Santen U.S. business, and our platform for securing U.S. market access is now in place. Nevertheless, achieving profitability has taken longer than expected due to the receipt of a complete response letter from the FDA citing issues with regard to STN1011700, for which we have filed a new drug application,

the removal of core Eyevance products from formularies, and product shortages caused by problems in the global supply chain.

In fiscal 2021, revenue increased 35.0% year on year, but due to the factors mentioned above this figure was significantly lower than the forecast, while profitability was also impacted. Currently, we are working on the normalization of product distribution, as well as measures to improve productivity, rebuilding the organizational structure, and to strengthen R&D functions, which is key to our future growth. We anticipate achieving several major milestones in the United States in fiscal 2022. First, is the launch of VKC treatment, Verkazia, in May 2022, following which we will focus on market penetration. The second milestone relates to STN1011700. In response to the complete response letter received in 2021, we implemented remedial measures and resubmitted the new drug application in May 2022. We believe this formulation with a novel mechanism of action can provide a new therapeutic option to glaucoma patients. For the Americas business, increasing sales and productivity are urgent issues, and we will accelerate our preparations to achieve profitability as early as we can.

Value Creation Highlights

Launch of Verkazia

This product is a prescription treatment for which we have obtained approval in the U.S., and is the only FDA-approved topical immunomodulator for the treatment of VKC in children and adults. The number of patients diagnosed with VKC exceeds 49,000,³ with more cases believed to go undiagnosed or overlooked. By raising awareness and providing treatment options for VKC, a rare disease, we are helping patients affected by this disease achieve greater independence in their daily lives.

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² A list of drugs compiled by the pharmacy benefit manager that are approved for prescription under insurance coverage

³ DelveInsight 2020 Vernal Keratoconjunctivitis (VKC) Epidemiology Forecast—2030.



EMEA: Continuing Its Steady Growth Trajectory

By integrating the region's diversity into business strategies, we will raise Santen's presence further as a global ophthalmology company in EMEA.

Strategy

31 EMEA: Continuing Its Steady Growth Trajectory

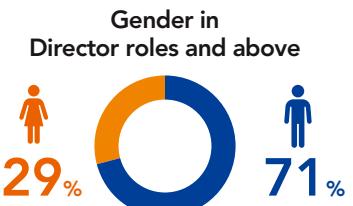
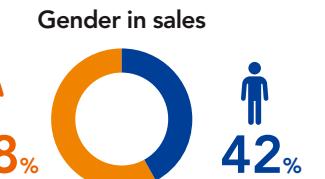
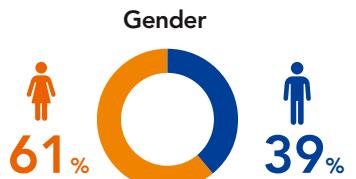


Luis Iglesias

Head of EMEA Business,
Head of North America Business

EMEA Human Capital Diversity

Our EMEA region extends to around 50 countries with about 750 employees of 45 different nationalities. Our overall regional female-to-male employee ratio stands at 61%:39% with an average age of 45. If you look at gender for medical representatives (MRs) and scientific affairs managers, the



Average seniority **5.7** years

Average age **45** years old

45 different nationalities in EMEA

ratio is 58%:42%. The prevailing rich diversity that the EMEA region offers and which we have leveraged is one of the key factors that has enabled us to develop a strong business over the course of the last few years.

Diversity and Business Strength

The EMEA region consists of a sophisticated network of countries with different healthcare systems and operating and regulatory environments. Our focus on working with this diversity as we pursue full-scale business expansion has allowed us to assess properly the business environment and calibrate the region's strategy accordingly. We leverage this sophisticated level of coordination in the region to achieve a similar level of collaboration internally between various functions ranging from market access to R&D and externally, for example with contract manufacturing organizations (CMOs). This has been fundamental to the execution of our regional business strategy and allowing us to develop our talent with global role opportunities based in EMEA.

Top-line contribution to Santen is at 16% for fiscal 2021, coupled with an increase in productivity in terms of

contribution profit margin that has improved from 27% to 33% since fiscal 2019 due to a disciplined cost-conscious approach. As a result of our penetration in the glaucoma and dry-eye space, which accounts for close to 90% of EMEA sales, our market share is increasing in a number of countries.¹ Our key products are contributing to this growth, resulting in an increase in share in 10 out of 12 key countries in EMEA.¹ In particular, we have the top market share¹ in 13 countries for glaucoma.

Our EMEA Pricing & Market Access team has shown an integral role in optimizing the value of our products to patients, from initial new product planning, to obtaining patient access with successful health technology assessments, showing cost containments and cost-utility and economic studies, all the way down the line to pricing management in light of loss of exclusivity and generic bridging. It is even more exciting to see that this Value & Access approach will be incorporated into our global framework to not only serve patients in the EMEA region, but to optimize and enhance the value and access of our products to patients globally.

The change in environment related to the COVID-19 pandemic also compelled us to accelerate our digital transformation in key areas such as switching to online medical education, direct-to-consumer activation and marketing personalization. The use of data and analytics alongside medical education delivered in novel and relevant ways improved learning accessibility and effectiveness for many.

Strategy

31 EMEA: Continuing Its Steady Growth Trajectory



EMEA: Continuing Its Steady Growth Trajectory

We will continue to grow our business while we constantly calibrate and improve our processes and optimize and leverage our resources. In EMEA, we have also been very keen to take the necessary actions to minimize short- and long-term impacts from change in external operating conditions such as the ongoing situation concerning Russia and Ukraine.

Latest Trends

Our glaucoma product portfolio has performed with gains in market share. *Tapcom* is one of our key growth drivers with further potential and *Cosopt* preservative-free formulation has fared well, overtaking the preservative formulation. As for *PRESERFLO MicroShunt*, we have a growing number of surgeons using it, with our surgical partners playing a key role in supporting them to get the best outcomes in all of their suitable patients.

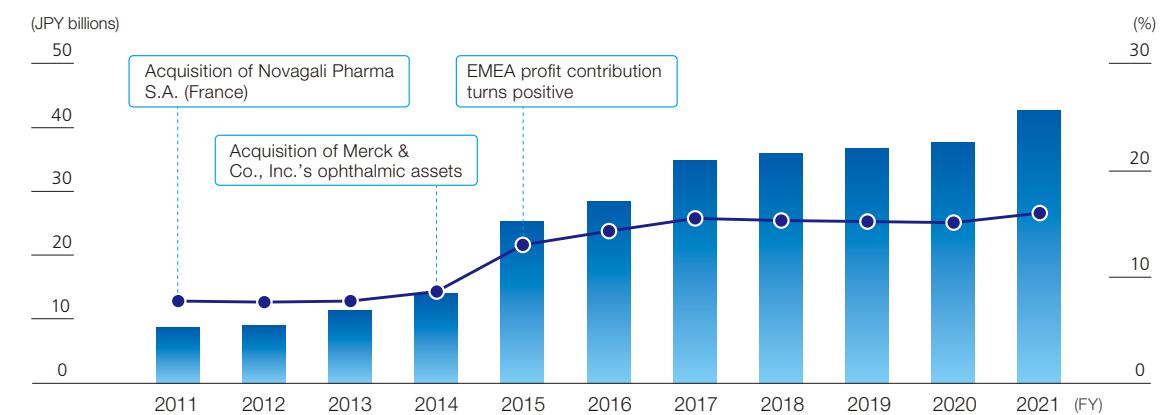
The trend of early treatment to stop the vicious cycle of dry eye has strengthened among both healthcare

professionals and patients. COVID-19 created a backlog for ophthalmologists to catch up with after the pandemic. We are working on a patient support program which will not only help patients to better understand their disease and ways of managing it but also to realize why it is important to stay on treatment in order to get better long-term relief from their dry eye.

Despite various hurdles related to the COVID-19 pandemic, clinical activities in EMEA successfully continued in fiscal 2021, including the recent completion of a pivotal trial, in parallel with three other ongoing clinical studies in dry eye and glaucoma. Through our emphasis on People Centricity we aim at better understanding patient needs and expectations to guide R&D directions.

While we will drive new products across the glaucoma and dry eye space in fiscal 2022, leveraging the diversity of our human capital pool will continue to remain the key factor to determine our success as a firm in supporting our customers and patients.

Revenue and Contribution to Total Revenue



Strategy

Catherine Curutchet

Head of France, Benelux,¹ North Africa
President of Santen S.A.S. France



On Diversity

What does diversity mean to you?

Diversity in an organization is multi-faceted, covering such wide angles as gender, professional experience and age. The more diversity you have, the more perspectives you can rely on to anticipate, plan and execute your business strategy wherein you are constantly faced with changes.

How have you promoted diversity in the organization?

The key is to ensure that there is diversity in your own team. Company-wide quota objectives on specific ratios are good tools to point out which direction the Company is heading, but in terms of effectively promoting a diverse work environment, respective diversities need to have representation. I believe human nature makes it difficult to make bias-free decisions—regardless of good intentions or whether or not you are aware of it.

How has acknowledging bias worked for you in promoting diversity at Santen?

I am leveraging my experience in France to be responsible for Benelux and North Africa, in addition to France. I think being aware of your own bias is first and foremost important. I spent the first sixteen years of my career in the consumer products space before spending the other half in the pharmaceutical industry. I believe constantly challenging yourself is important and this is why upon my current appointment I focused on getting the appropriate level of representation of diversity in my team, including but not limited to professional experience, gender, age, and cultural background.

¹ Belgium, the Netherlands and Luxembourg

Strategy

Product Development

Santen is working to support short- and medium-term growth by developing and launching products in its core business areas with a focus on glaucoma, dry eye and allergies. At the same time, we are conducting research and development in new therapeutic areas and treatments that will support future growth. We are stepping up our efforts for innovation in areas such as digital health and cell therapy, and are working on new disease areas including myopia and ptosis with a view to providing value to patients through the out-of-pocket market. Having identified which diseases to target based on unmet needs and the maturity of technologies, Santen formulates disease strategies by comprehensively considering the kinds of therapeutic methods and services we can and should contribute to, taking into account the impact on society and medical care, and the suitability of our technologies and experience.

**Key Achievements
of Ophthalmology
Innovation Center
(FY2021)**

- **STN1010905**—Started P2a (meibomian gland dysfunction)
- **STN1012700**—Confirmed safety and tolerability in P1 (myopia; China)
- **STN1013400**—Confirmed safety and tolerability in P1 (myopia)
- **STN1013600**—Confirmed safety and tolerability in P1 (presbyopia)

**Key Achievements
of Product
Development Division
(FY2021)**

- **STN1007603**—Obtained approval in U.S. and China
- **STN1008903**—Filed in Japan
- **STN1013900**—Filed in Asia
- **STN2000100**—Obtained approval in Japan and Asia

33 Product Development



Reza Haque, MD, Ph.D

Head of Ophthalmology
Innovation Center

**Understand patients' circumstances
and address eye diseases in
collaboration with external partners**

Santen is working to create products by considering patient needs, scientific understanding, and medical perspectives, while continually being people-centric. In order to strategically create new products for target diseases, we, the Ophthalmic Innovation Center, collect patients' real voices and visualize the patient journey¹ to accurately grasp the progression of symptoms, treatment methods, and patients' circumstances. This process enables us to clarify the points that should be addressed in each disease and the product concept, and then establish an appropriate disease strategy. In addition, our pipeline in the early stages of research is mapped on two axes: the number of patients with a given disease and the degree of potential therapeutic contribution to the patients. Through this mapping we identify areas in our pipeline to strengthen and focus on. Based on these strategies and priorities, we engage with universities, research institutes, pharmaceutical companies, and startup companies worldwide to strengthen

our networks and collaborations. This approach is one of Santen's strengths, and leads to the development of new drug candidates and therapeutic technologies. We have created a collaborative research and development framework with academic institutions such as the Singapore Eye Research Institute (SERI) and University College of London (UCL). In addition, through our alliances we have been able to find drug candidates for myopia and Fuchs endothelial corneal dystrophy. We are also working toward the objective of increasing the probability of success in product creation, including by increasing the percentage of products that advance to the next stage of clinical trials. For diseases where it is difficult to establish clinical efficacy indicators, we perform biomarker exploration and translational research.² In these and other ways, we will contribute to the creation of new products from a scientific standpoint and from the patient's perspective.

¹ A representation of the patient's Behavior, Thoughts, Feelings, and other processes from the patient's recognition of a disease or symptom to the patient's eventual treatment, including hospital visits and medication

² Bridging research that links basic research, clinical research, and medical treatment to efficiently and effectively commercialize results that contribute to medical development

Strategy

33 Product Development

Strategy

Product Development



Peter Sallstig, MD, MBA

Chief Medical Officer
Product Development Division

Develop products efficiently to meet true unmet needs by strengthening strategies and execution capabilities

The Product Development Division's mission is to develop and deliver products that meet the needs of patients as quickly as possible, without compromising quality. In order to achieve this goal, we maintain the following three deliverables as priorities:

- 1) develop and implement a development strategy that reflects both patient insights and market needs; 2) continuously maximize product value through life cycle management; and 3) strengthen global scientific and operational excellence, supporting our ability to accomplish the development objectives we set.

In fiscal 2021, we achieved several important pipeline milestones. In Japan, examples include filing for approval of STN1008903, a new formulation of *Diquas* that reduces applications needed per day, and obtaining approval for *Eybelis* as a single-dose eye drop with improved safety. In the U.S., we obtained approval for *Verkazia*. At the same time, we filed for approval of *Verkazia* in China as part of our regional expansion. We also refiled STN1011700 in the U.S. in May 2022. These achievements are the result of our efforts to create products that meet the needs of patients by closely communicating with them, as well as with regional health authorities and agencies, and strategically implementing development.

We have been able to minimize delays as well as accelerate the development plans for our late-stage clinical pipeline, despite the COVID-19 pandemic that has been ongoing since



Kenji Morishima

Head of China Product Development Department

The mission of the China Product Development Department is to develop and deliver drugs to meet the needs of patients as quickly as possible. Until now, for products already launched outside China, the development process involved bridging studies to demonstrate that there is no significant variation in efficacy of products due to inter-ethnic differences between patients in China and in other regions. The need for this creates a time lag between product launches in other regions and in China. Of course, one of our most important missions to accomplish by 2025 is to obtain early approval in China for products already launched in other regions. However, looking ahead to 2030, we would also like to integrate the pipeline in China with the global pipeline from an early stage, through which China would be able to participate in

multi-regional clinical trials (MRCT) for new products, file for approval and launch products within the same timeframe as other regions. To achieve this, we are working to secure skilled human resources, build a robust development process and construct a framework capable of high-quality development. We will also formulate competitive development strategies that take full advantage of Santen's strengths, i.e., having a development base in China and knowledge of application routes specific to this region. Backed by both an extensive pipeline and operational excellence, we will accelerate innovation at the China Product Development Department in order to bring new products to patients in China faster, and continue to contribute to Happiness with Vision.



2020. This success can be attributed to our constant efforts to implement new technologies to improve the execution of remote clinical trials, and the close communication between regional clinical development members and study sites. Digitalization is indispensable for the further pursuit of global operational excellence. These technologies are advancing day by day; hence, we are keeping our eyes on the development of new technologies worldwide and will quickly adopt those that are consistent with our clinical trial strategies. We will continue to contribute to Happiness with Vision for our patients by effectively developing a pipeline based on our strategy of continuously delivering products to patients that meet their true needs.

Strategy

33 Product Development

Strategy

Product Development



Taking on a rare allergy mainly affecting children with our proprietary technology "Novasorb"



Henri Criseo

Director, Project Management Research & Development (Global)
Project Management Group
Product Development Division

Vernal keratoconjunctivitis (VKC) is a rare allergy mainly affecting children and adolescents. It can feature severe symptoms such as a burning sensation, eye pain and pruritus that can significantly impair patients' quality of life, and may cause corneal damage and loss of vision. If patients develop symptoms at school age, they may need to cool their eyes frequently with a clean towel to relieve symptoms, or wear sunglasses due to photophobia when they go out, which may interfere with their daily life and ability to follow classes.

Before Santen developed Verkazia, the only treatments were mainly corticosteroids, which cannot be used over the long term and can include significant side effects, or the empirical use of ciclosporin A through hospital compounded formulations. Santen therefore decided to develop its own formulation of ciclosporin A using Novasorb, a cationic emulsion technology that improves the corneal bioavailability of the active ingredients compared to more standard formulations. This is the same innovative technology that is used in Cationorm, Ikervis and more recently STN1013001. Novasorb technology was developed by Novagali Pharma, which Santen acquired in 2011. This technology led to the

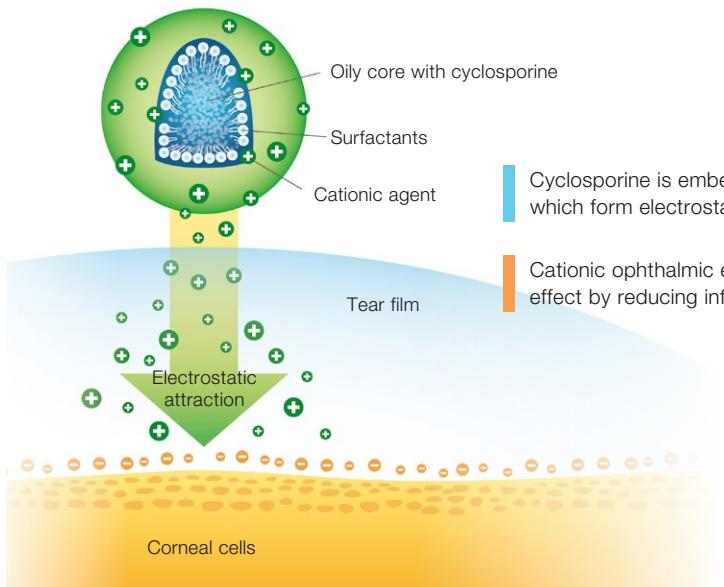
development of Verkazia with a specific adapted dosing regimen to treat VKC, keeping in mind that the product had to be well tolerated by the patients as well as being highly effective.

All those medical requirements were engraved in the development team's mind so that each step would be reflected in the final product. Verkazia demonstrated rapid improvement in the symptoms of patients with severe VKC in large-scale clinical trials. This resulted in the approval and launch of the first product with a VKC indication in the EU. It was recently approved in Asian countries, Canada, the U.S. and China as well.

At Santen, Patient and People Centricity is at the forefront,

and we truly believed from the beginning of development that bringing an innovative, standardized and effective product to VKC patients and their caregivers would help relieve the effects of this condition. One caregiver provided us with the following message. "The Verkazia eye drops are amazing. I would like to thank all of you for coming up with this drug and making it happen. Our lives have changed dramatically, and our family can't thank you enough." It is messages such as these that inspire and drive us forward in developing treatments for patients such as those affected by VKC. We are proud to make available a new and effective therapeutic solution that helps improve the quality of life of patients with this rare and burdensome condition.

Novasorb Technology



Cyclosporine is embedded in positively-charged nanosized droplets, which form electrostatic attractions with the anionic ocular surface¹

Cationic ophthalmic emulsion provides an additional palliative effect by reducing inflammation and discomfort¹



Strategy

33 Product Development

Strategy

Product Development

Development Status

Products Launched in FY2021	37 products including STN1011702 (<i>Eybelis Mini</i> , glaucoma, Japan)
Products Approved in FY2021	47 products including STN1007603 (<i>Verkazia</i> , vernal keratoconjunctivitis, U.S.) and STN2000100 (<i>PRESERFLO MicroShunt</i> , glaucoma, Japan/Asia)

For the latest development status of main projects in the pipeline, please see the Company's website.

Pipeline Development Status (As of May 31, 2022)

	Clinical development plan in preparation ¹	P1	P2	P3	Filed
Glaucoma	STN1014000 (Asia, filing) STN1008507 (<i>Tapros</i> with new instillation system, JP, filing) STN1011103 (<i>Tapcom</i> with new instillation system, JP, filing)		STN1012600 (JP, EU, U.S.)	STN1011101 (CN) STN1013001 (Asia, EU) STN1013900 (JP)	STN1011700 (U.S.) STN1013900 (Asia)
					STN1008903 (JP)
					STN1013500 (JP) STN1000501 (CN)
Dry eye					
Allergies				STN1011402 (JP)	
Fuchs endothelial corneal dystrophy			STN1010904² (U.S., France, India)		
Meibomian gland dysfunction			STN1010905 (JP)		
Myopia	STN1013300	STN1012700 (CN) STN1013400 (JP)	STN1012700 (Asia)	STN1012700 (JP)	
					STN1012701³ (EU)
Presbyopia	STN1013600 (U.S., P2a)	STN1013600 (JP)			
Ptosis	STN1013800 (JP, P3/Asia, filing)				
Retinitis pigmentosa	STN6000100 (P3)				

Discontinued development of STN1010900 (sirolimus, intravitreal injection) based on a reassessment of its business feasibility

Out-licensed STN2000100 (glaucoma implant device) to U.S.-based Glaukos in the Americas, Australia and New Zealand

¹ Includes projects in the non-clinical stage, projects for which clinical trial protocols are being formulated, and projects for which applications are planned.

² Santen retains the option right for exclusive license for this program. This development code to be formally assigned to the product when Santen obtains exclusive license upon the completion of Phase II trial.

³ Conducted by Sydnexis

Strategy

37 Digital Transformation (DX)
Supporting Business and Management



Digital Transformation (DX) Supporting Business and Management

One of the key management strategies at Santen is to enhance digital capabilities from a company-wide perspective. In the global healthcare market, we see an acceleration toward business models that leverage digital technologies to create new products and services. We aim to grow medium- to long-term corporate value by becoming even more competitive and engaging in advanced digital governance.



Minori Hara
Chief Digital &
Information Officer

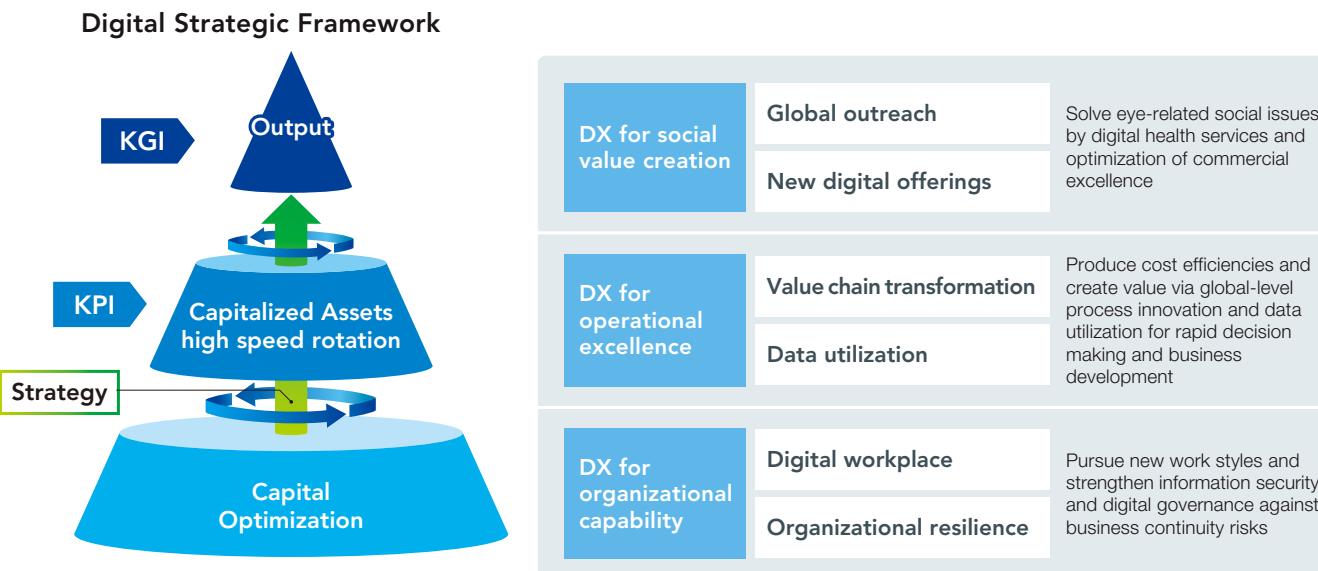
The Santen digital strategy consists of a three-layered structure: DX for social value creation, DX for operational excellence, and DX for organizational capability.

DX for social value creation means solving social issues by introducing digital health services and optimizing commercial excellence through digitalization.

DX for operational excellence produces cost efficiencies and creates value via global-level process innovation and data utilization. In this way, we facilitate rapid decision making and business development.

DX for organizational capability inspires new work styles in digital workplaces. It also strengthens information security and digital governance against business continuity risks.

The organic integration of these initiatives will ensure the success of Santen business and management.



1 Strengthening Digital Governance

In February 2022, Santen became a certified Digital Transformation Business Operator under the Ministry of Economy, Trade and Industry.

The certification recognized our efforts to meet the certification criteria under the Digital Governance Code, which stipulates actions that business managers are expected to implement in order to boost corporate value, and that the Company conducts appropriate information disclosure to its stakeholders.



Strategy

37 Digital Transformation (DX) Supporting Business and Management

Strategy

Digital Transformation (DX) Supporting Business and Management

Furthermore, our information security policy conforms to ISO/IEC 27001 and we continue to strengthen initiatives to protect stakeholders. In addition to instituting cybersecurity processes, our response to information security risk also includes global training programs. We gamify these trainings for efficient learning related to cybersecurity in daily work scenarios to maintain a high level of security.

And we are implementing a next-generation enterprise resources planning (ERP) system as one means to enhance internal controls. Santen has created a team of highly specialized personnel in an agile, cross-regional organizational structure. Under the leadership of this team, we pursue a global project aimed at standardizing internal processes and improving transparency to accelerate the transformation of our business model. Leveraging standardized data infrastructure as an important management resource, we will execute more agile management decision-making, improve profitability, and create new value.

2

Business Model Transformation: Accelerating Innovations in Ophthalmology

We are transforming our business model through the use of digital technologies across the entire value chain, from R&D and production to sales and marketing. We are converting our plants to smart factories, including in Shiga and at new facilities under construction in Suzhou. These efforts, together with the ongoing introduction of the next-generation ERP platform, are uncovering issues in the value chain, allowing us to optimize costs and create new value.

Santen is also making progress in building out our online platform for healthcare professionals and medical institutions, leading to the further development of an ophthalmic ecosystem. As an example, in February 2022, we launched the Santen Eyecare Education (SEE) portal, beginning in France and the Netherlands, and we are rolling out this program in other countries as well. The environment related to education has undergone changes since the outbreak of COVID-19. These changes include fewer opportunities for medical professionals to interact with each other. However, our new system provides interactive learning opportunities and contributes to the educational needs of local ophthalmologists.

In January 2020, we entered into a partnership with the International Telecommunication Union (ITU), a specialized agency of the United Nations. Our goal in this partnership is to support the *Be He@lthy, Be Mobile* initiative between ITU and the World Health Organization. As part of this initiative, we are developing digital health programs for developing countries in Asia and Africa to raise awareness and health literacy about myopia and myopia prevention. As a specialized company dedicated to ophthalmology, we will contribute to the further development of the ophthalmic ecosystem.



3

DE&I: Utilizing Human Resources

We were quick in developing a remote work environment in response to COVID-19. Santen aspires to Become A Social Innovator, orchestrating and mobilizing key technologies and players around the world, to deliver happiness through vision, and we will continue to explore new work styles. As our global expansion gains momentum, we adopted a new Work from Anywhere program in fiscal 2021. Under this policy, employees choose where and when to work in a flexible manner, carrying out their duties efficiently, with independence and autonomy. The Company is also improving accessibility to digital tools for visually impaired employees. Santen executes work-style reform and Diversity, Equity & Inclusion (DE&I) through digital means to allow people from diverse backgrounds to participate fully. In this way, we attract and benefit from talented individuals who share our corporate culture. We support each individual to maximize their skills and abilities, thereby raising the overall capability of the organization. We began offering educational programs on AI and data dashboard building, which 350¹ employees have taken and are now using to solve business issues.